

# REACH provisions for substances used in R & D

## Research and development activities

### Scientific research and development

Any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year.

There is no specific exemption from registration for such R & D because substances in those quantities do not have to be registered in any case. The provisions of authorisation and restriction processes shall not apply.

If the scientific R & D is carried out in cooperation with other companies, the provisions concerning the classification/labelling and the information in the supply chain apply.

### Product and process oriented research and development (PPORD)

Any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance.

### PPORD in quantities below 1 tonne per year

Substances manufactured or imported in those quantities do not have to be registered.

Concerning authorisation, the annexe XIV of REACH (list of substances subject to authorisation) shall specify if the authorisation requirement shall not apply to PPORD, as well as the maximum quantity exempted. In a similar way, the restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (REACH annexe XVII) shall specify if the restriction on a substance shall not apply to PPORD, as well as the maximum quantity exempted.

If the PPORD is carried out in cooperation with other companies, the provisions concerning the classification/labelling and the information in the supply chain apply.

### PPORD in quantities of 1 tonne per year or more

Substances manufactured or imported for the purpose of PPORD can be exempted from the duty to register for a period of 5 years. To be exempted a company needs to submit a PPORD notification to the European Chemicals Agency (with the identity and classification of the substance, the estimated quantity and the list of customers). Upon request, the Agency may further extend this exemption for up another 5 years, or 10 years for the development of medicinal products (for human or veterinary use) as well as for substances that are not placed on the market. The exemption from registration for the purpose of PPORD applies provided that the manufacturer or the importer carries out the PPORD by himself or in cooperation with listed customers<sup>1</sup>, in quantities limited to the purpose of PPORD.

The Agency could decide to impose conditions to ensure that the substance will be handled only by staff of listed customers in reasonably controlled conditions and will not be made available to the general public and that remaining quantities will be re-collected for disposal after the exemption period.

Concerning authorisation, the annexe XIV of REACH (list of substances subject to authorisation) shall specify if the authorisation requirement shall not apply to PPORD, as well as the maximum quantity exempted. In a similar way, the restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (REACH annexe XVII) shall specify if the restriction on a substance shall not apply to PPORD, as well as the maximum quantity exempted.

If the PPORD is carried out in cooperation with customers, the provisions concerning the classification/labelling and the information in the supply chain apply.

*1. If a downstream user (DU) intends to use a substance for PPORD without being listed as one of the selected customers in a PPORD notification, provided the risks to human health and the environment are adequately controlled, the DU is exempted from preparing a chemical safety report for the use under PPORD. He has otherwise the same obligations under REACH as for any standard substance.*